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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,990	08/18/2000	Riley Rees	3572-0101P	6659

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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/640,990

Applicant(s)

REES, RILEY

Examiner

David M. Naff

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10,11,13-15 & 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10,11,13-15 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

An amendment of 5/17/04 canceled claims 1, 3-7 and 16-20, and added new claims 23-25. Claims 2, 8, 9, 12, 21 and 22 were canceled previously.

5        Claims examined on the merits are 10, 11, 13-15 and 23-25, which are all claims in the application.

Reference 5 (5,269,917) has been considered and listed on form PTO-892. If applicants want Reference 29 (book) considered, another form PTO-1449 must be supplied along with a copy of the reference. If  
10        applicant wants the entire book considered, a copy of the entire book must be furnished. It is suggested that applicant select the most pertinent pages in the book, and supply only these pages rather than the entire book.

The text of those sections of Title 35, U.S. Code not included in  
15        this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 10, 11, 13-15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rees et al (6,197,330 B1), (5,972,332), (6,440,452 B2) or (6,399,898 B2) in view of Dionne et al (5,786,216)  
20        and Shapiro et al (6,425,918 B1).

Claim 10 and claims dependent thereon require providing an unsealed enclosure, introducing a solid support material into the unsealed enclosure, sealing the enclosure, and the sealed enclosure containing the support is immersed in a culture of cells, and the

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cells migrate into the sealed enclosure and attach to the support.

Claim 23 requires foreskin-derived cells.

Rees et al ('330), ('332), ('452) and ('898) disclose attaching  
cells to a solid support, placing the cell-containing solid support  
5 into an enclosure and sealing the enclosure. The enclosure may have  
pores large enough for cells to exit the enclosure, and the sealed  
enclosure may be sterilized with ethylene oxide. For example, see  
( '330) (col 2, lines 33-35) and (col 13, lines 5-10).

Dionne et al disclose injecting cells into a capsule which may  
10 contain a hydrogel support. See the abstract and col 4, lines 24-26.

Shapiro et al disclose implanting a sponge support into a patient  
and then after blood vessels have invaded the support, injecting cells  
into the support (col 5, lines 15-25). The cells may be from foreskin  
(col 30, line 7).

15 The method disclosed by the Rees et al patents is the same as  
presently claimed except that in the claims the cells are attached to  
the support by the cells migrating from a cell culture into the  
enclosure after sealing.

It would have been a matter of obvious choice depending on  
20 individual preference and convenience to modify the method of the Rees  
et al patents by putting the support into the enclosure, sealing the  
enclosure and then allow cells to migrate into the enclosure and  
attach to the support as suggested by Rees et al disclosing that cells  
can exit the enclosure through the pores of the enclosure and Dionne  
25 et al disclosing injecting cells into a capsule that may contain a

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support and Shapiro et al disclosing injecting cells into a sponge support after the support has been implanted in a patient. If cells can exit the enclosure through pores, it would have been obvious that cells can enter the enclosure through pores of the enclosure, and to  
5 allow cells to enter the enclosure by cells migrating through the pores instead of by injection as disclosed by Dionne et al and Shapiro et al would have been a matter of obvious choice. Dionne et al and Shapiro et al suggest that cells can be attached to the support after the enclosure of Rees et al is sealed as an alternative to attaching  
10 cells to the support before the support is put in the enclosure, and it is clear from Rees et al that this can be accomplished by cells migrating through pores of the enclosure instead of by injecting. No unexpected result is apparent. The limitations of the dependent claims are disclosed by Rees et al or would have been obvious in view  
15 of conditions disclosed by Dionne et al and Shapiro et al. Shapiro et al suggested cells from foreskin, and using these cells would have been merely a matter of individual preference for certain cells.

#### ***Response to Arguments***

Applicant urges that the claims require cells to migrate into the  
20 enclosure rather than be injected. However, for reasons set forth above, allowing cells to migrate into the enclosure would have been an obvious alternative. No unexpected result has been established in allowing cells to migrate through pores rather than be injected.

***Claim Rejections - 35 USC § 103***

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 10, 11, 13-15 and 23 above, and further in view of Endo et al (5,705,382) (newly applied).

Claim 24 additionally requires heat sterilizing the sealed enclosure, and after cells migrate into the enclosure require freezing the sealed enclosure containing cells.

Endo et al disclosed preserving immobilized cells by freezing (col 1, lines 36-40).

When carrying out the method of Rees et al as set forth above, it would have been obvious to freeze the enclosure containing the cells to preserve the cells as suggested by Endo et al. Rees et al disclose sterilizing with ethylene oxide, and to use heat sterilizing in place of ethylene oxide would have been a matter of obvious choice since heating is a well known way of sterilizing. As noted above, Shapiro et al suggest foreskin cells

***Double Patenting***

Claims 10, 11, 13-15 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,197,330 B1 or claims 1-6 of U.S. Patent No. 5,972,332 or claims 1-22 of U.S. Patent No. 6,440,452 B2 or claims 1-21 of U.S. Patent No. 6,299,898 B2 in view of Dionne et al and Shapiro et al.

For the reasons set forth above in the 103 rejection, it would have been obvious in view of the disclosures of Rees et al and Dionne et al and Shapiro et al allow cells to migrate into the enclosure of the claims of patent ('330), ('332), ('452) or ('898) after the enclosure has been sealed to attach cells to the support in the enclosure.

### ***Response to Arguments***

The response to arguments above in regard to the 103 rejection also applies to this rejection.

### ***Double Patenting***

Claims 24 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting over the claims of the Rees et al patents in view of Dionne et al and Shapiro et al as set forth above and further in view of Endo et al for reasons set forth above in the 103 rejection when applying Endo et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
7/26/04